REMARKS

A. Status of the Claims

Claims 67-69 and 71-72 are pending and currently under examination. Claims 67 and 68 are amended herein; claims 70, 73, and 74 are cancelled; no claims are added.

Claims 67-74 are rejected under 35 U.S.C. §102(b) for allegedly being anticipated by WO 02/07773 to Waugh ("Waugh").

Claims 67-69, 71, and 73-74 are provisionally rejected on the ground of non-statutory obviousness type double patenting for allegedly being unpatentable over claims 51-55, 64-73, 77-118, 146, and 149-150 of U.S. Patent Application No. 10/591,732.

Claims 67-69 and 72-74 are provisionally rejected on the ground of non-statutory obviousness type double patenting for allegedly being unpatentable over claims 78-80, 84, and 90-94 of U.S. Patent Application No. 10/591,485.

Claims 67-69, 71, and 73-74 are provisionally rejected on the ground of non-statutory obviousness type double patenting for allegedly being unpatentable over claims 1-20 of U.S. Patent Application No. 12/647,677.

Claims 67-69, 71, and 73-74 are provisionally rejected on the ground of non-statutory obviousness type double patenting for allegedly being unpatentable over claims 9 and 11 of U.S. Patent Application No. 11/816,602.

B. Amendments to the Claims

Applicants have amended claim 67 to specify that the carrier and the biologically active protein "non-covalently and directly associate." Support for this amendments is found, for example, in ¶ [0068], which states that "[i]n all aspects of the present invention, the association

between carriers as described herein and the biologically active agent is by non-covalent interaction, which can include, for example, ionic interactions, hydrogen bonding, van der Waals forces, or combinations thereof." Support also occurs, e.g., in ¶ [0065], where it is stated that "... certain substances can be transdermally delivered by use of certain positively charged carriers alone, without requiring the inclusion of a negative backbone." The absence of an intervening negative backbone component clearly indicates a direct association between the carrier and the biologically active protein. The specification further provides that in these cases, the substances or derivatives thereof have sufficient functionalities to associate with the carriers of the instant invention non-covalently, again indicating a direct association. Additional support occurs, e.g., at ¶¶ [0099], [0103], [0107], and [0111]. Furthermore, direct association between the carrier and its cargo molecule is graphically depicted in Figures 1 and 2.

Claim 67 also is amended to recite that the biologically active protein "excludes insulin, vascular endothelial growth factor (VEGF), and antibody fragments", which incorporates aspects of previous claim 70. Claim 70 is cancelled as redundant in view of this amendment, along with claims 73 and 74.

Applicants also have amended claim 68, to correct its dependency.

Accordingly, the amendments raise no issues of new matter.

C. Applicants' Claims Are Novel Over Waugh

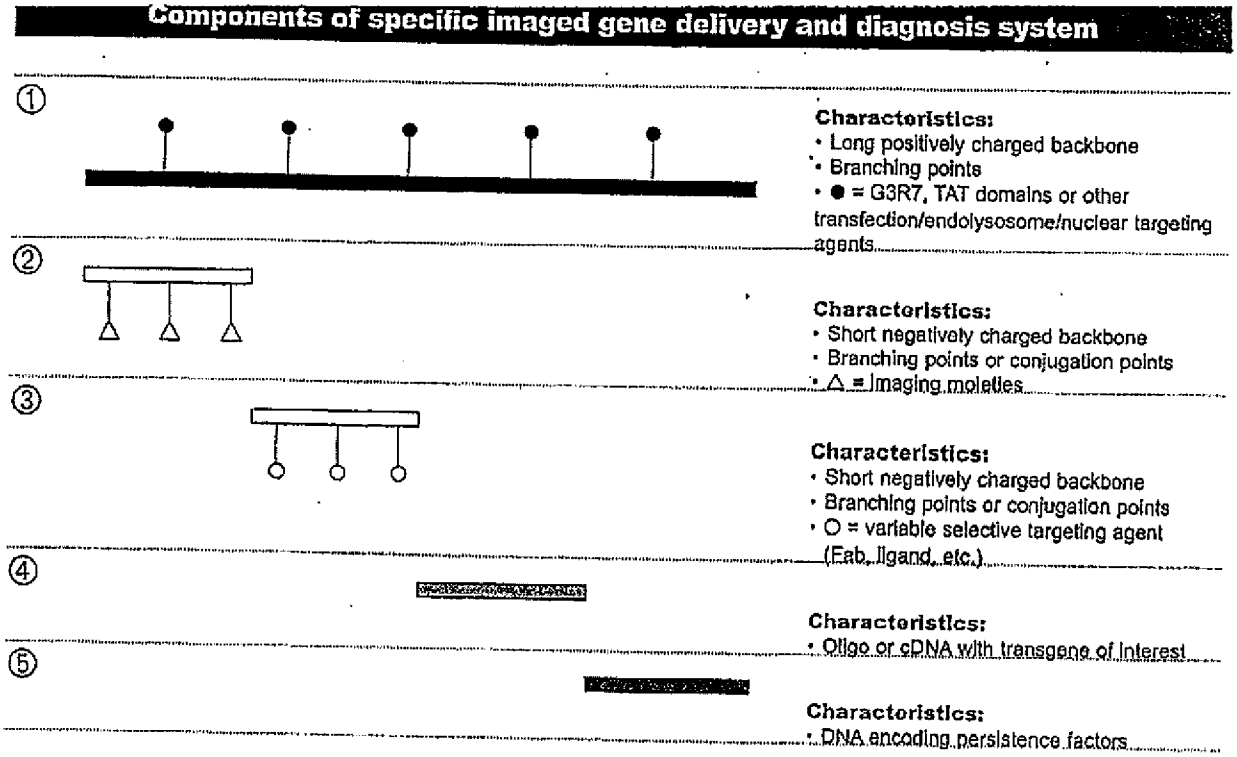
Applicants respectfully traverse the rejection of claims 67-74 under 35 U.S.C. §102(b) for allegedly being anticipated by Waugh. Waugh fails to disclose all of the features recited in Applicants' presently pending claims. Accordingly, the rejection should be withdrawn. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed.

Cir. 1987) (stating that claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference).

Claim 67 of the present application requires "a biologically active protein" and "a carrier", which "comprises a polypeptide having attached positively charged branching groups ... ." Furthermore, claim 67, as amended, requires that "the carrier and the biologically active protein non-covalently and directly associate" and also that "the biologically active protein excludes insulin, vascular endothelial growth factor (VEGF), and antibody fragments". The remaining claims, claims 68-69 and 71-72, each depend directly or indirectly from claim 67, thus also requiring these features.

In contrast, Waugh does not disclose a composition where the biologically active protein "excludes insulin, vascular endothelial growth factor (VEGF), and antibody fragments" and where "the carrier and the biologically active protein non-covalently and directly associate," as required by the presently-amended claims. In Waugh, both cosmeceutical and therapeutic agents are described as "biological agents." *See, e.g.*, Waugh, page 3, lines 32-33, page 15, line 20. Such biological agents include "biologically active proteins", as Waugh lists a number of biologically active proteins as examples of such. *See, e.g.*, Waugh, page 15, lines 33-34. Critically, to the extent that "biological agents" are present in Waugh's compositions, and are not "insulin, vascular endothelial growth factor (VEGF), and antibody fragments" ***they are attached to a negatively charged backbone***.

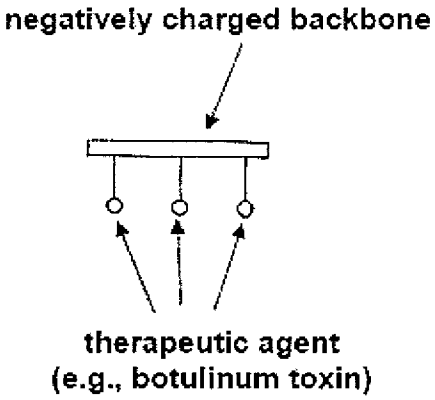
For example, in the "Summary of the Invention" section, Waugh states that its compositions comprise "a third negatively charged backbone having a plurality of attached biological agents." Waugh, page 3, lines 28-29. Furthermore, this arrangement is illustrated in Figure 1 of Waugh, an excerpt of which is reproduced below:



As stated in Waugh's specification, Figure 1 shows that the therapeutic agents (e.g., biologically active proteins) are attached to "a short negatively charged backbone":

> In this figure, the components are shown as (1) a solid backbone having attached positively charged groups (also referred to as efficiency groups shown as darkened circles attached to a darkened bar), for example $(Gly)_{n1}$-$(Arg)_{n2}$ (wherein the subscript nl is an integer of from 3 to about 5, and the subscript n2 is an odd integer of from about 7 to about 17) or TAT domains; (2) a short negatively charged backbone having attached imaging moieties (open triangles attached to a light bar); (3) ***a short negatively charged backbone having attached targeting agents and/or therapeutic agents (open circles attached to a light bar)***; (4) an oligonucleotide, RNA, DNA or cDNA (light cross hatched bar); and (5) DNA encoding persistence factors (dark cross hatched bar).

Waugh, pages 5-6. In other words, the attachment between the short negatively charged backbone and the therapeutic agents (e.g., biologically active proteins) is represented by the structure associated with reference numeral 3 in Figure 1, as reproduced below with annotations:



Waugh states that the use of negatively charged backbones with therapeutic agents and other components allows the formation of complexes with a positively charged backbone without the need to precisely position the therapeutic agent on a particular location on the positively charged backbone:

> By placing these components on a negatively charged backbone, the invention obviates the need for attaching components in precise locations on a positive backbone as employed in other strategies (increasing complexity and expense and decreasing efficiency to a level that no successful combination has yet been reported due to steric limitations).

Waugh, page 5. Thus, the formation of Waugh's complexes that contain biological agents (such as a biologically active protein excluding insulin, vascular endothelial growth factor (VEGF), and antibody fragments) ***is mediated by the interaction between the positive and negative charges on the positively charged backbone and negatively charged backbone, respectively.*** Accordingly, Waugh does not disclose a composition where "the carrier and the biologically active protein non-covalently and ***directly*** associate," and the biologically active protein is ***not*** "insulin, vascular endothelial growth factor (VEGF), and antibody fragments", as required by the present claims (emphases added).

Because Waugh does not disclose all of the features recited in the present claims, the rejection of claims 67-69 and 71-72 under 35 U.S.C. § 102(b) should be withdrawn. Applicants therefore respectfully request reconsideration and withdrawal of this ground of rejection.

D. Double Patent Rejections

Applicants respectfully request that the provisional obviousness-type double-patenting rejections set forth in the Office Action be held in abeyance, as the co-pending applications relied upon by the Office Action for the double-patenting rejections have not yet issued. Applicants reserve the right to address these double patent rejections at a later date, by filing a terminal disclaimer or by submitting arguments that the co-pending claims do not constitute double patenting.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of all objections to and rejections of claims, and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 50-3732, Order No. 13720-105068US2.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 50-3732, Order No. 13720-105068US2.

Respectfully submitted,
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